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5600 Fishers Lane,  
Rockville, MD 20857

Attention: Claudia Grillo

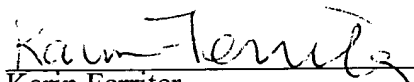
Dear Ms. Axelrad:

The attached application for patent term extension of U.S. Patent No. 4,937,078 was filed on June 7, 2004, under 35 U.S.C. § 156.

The assistance of your Office is requested in confirming that the product identified in the application, SURPASS® (diclofenac sodium), has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first permitted commercial marketing or use in animals, and that the application for patent term extension was filed within the sixty-day period after the product was approved. Since a determination has not been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act, or a method of manufacturing or use of such a product, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156.

Inquiries regarding this communication should be directed to the undersigned at (703) 306-3159 (telephone) or (703)872-9411 (facsimile).

  
Karin Ferriter  
Senior Legal Advisor  
Office of Patent Legal Administration  
Office of the Deputy Commissioner  
for Patent Examination Policy

cc: Paul E. Dietze  
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